UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	Docket No. 1:10-cv-286
	)	Alexandria, Virginia
v.	)	
	)	September 10, 2010
DAVID KAPPOS, *et al.*	)	11:11 a.m.
	)	
Defendants.	)	

TRANSCRIPT OF HEARING

BEFORE THE HONORABLE CLAUDE M. HILTON

UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff: Peter D. Keisler, Esq.
C. Frederick Beckner, III, Esq.

For the Defendants: Dennis C. Barghaan, Jr., Esq.
Monika L. Moore, Esq.
John P. Corrado, Esq.

Court Reporter: Tracy L. Westfall, RPR, CMRS, CCR

Proceedings reported by machine shorthand, transcript produced by computer-aided transcription.

P R O C E E D I N G S

THE CLERK: Civil Action 2010-286, *The Medicines Company v. David Kappos, et al.*

MR. CORRADO: Good morning, Your Honor. Jack Corrado for the movant.

MR. KEISLER: Good morning, Your Honor. Peter Keisler for The Medicines Company.

MR. BARGHAAN: Good morning, Your Honor. Dennis Barghaan on behalf of the defendants. With me, as always in this case, is Monika Moore from my office.

MR. CORRADO: Your Honor, as I'm sure the Court appreciates, no lawyer relishes the prospect of coming before the Court asking for relief to intervene just so he can appeal the ruling of the Court. But I think as the Court will also appreciate, the real harm to my client, APP Pharmaceuticals, the real harm is a consequence of the ruling.

There's been a lot of suggestion in the briefs of MDCO, and I think all of the cases cited by the government's brief talk about a different situation, a situation in which parties are trying to intervene into an *ex parte* proceeding, a PTE extension. That's not the situation here.

The harm is not a consequence of what any agency did in this case. The harm to my client is the fact that, as a practical matter, practical effect of this Court's ruling, a patent, the '404 patent, that should have expired has not

expired. So all of the effort that my client has put into its abbreviated new drug application, all of the efforts in development and marketing, with the expectation that as soon as the FDA issues its approval, my client can begin to enter the market immediately with a competitive drug to Angiomax, all of that has been suspended, and the time when my client can compete without the specter of this patent has been extended to a period that is uncertain.

THE COURT: That's not exactly true though, is it, because your client would have to get FDA approval and would have quite a process before they could go into the market in any event?

MR. CORRADO: That's correct.

THE COURT: Might not get FDA approval so it may be somewhat speculative as to whether they'd be damaged at all or not.

MR. CORRADO: I would submit, Your Honor, that the harm is not speculative. Even if the harm were speculative -- even if the harm were contingent, and the *Teague* case, which we've cited in our brief, *Teague v. Bakker* is the case that's controlling. The issue really is intervention. The issue isn't standing. The issue is intervention.

With respect to intervention, the issue is whether there's a significant protectable interest. *Teague* said that interest can be contingent. In *Teague,* the issue was whether or

not a judgment would later result which might create some rights. The harm to APP Pharmaceuticals is, we think, not contingent. There is a patent, the '404 patent, with its penumbra of restrictions and encumbrances, whatever they may be, whatever they may be, that stand in the way of my clients doing what it would otherwise be entitled to do.

If this patent had expired, which we believe it did and should have, if it expired, all of those encumbrances, all of those restrictions, all of those bars to market entry would have been gone, should now be done, but they're not.

The fact that they're not creates an injury to my client. That's an injury that we have an interest in protecting. Clearly, I think, under *Teague*, and especially given the contingent, the fact that *Teague* said you can have a contingent interest in the outcome, that is a significantly protectable interest. That interest is sufficient, especially now that the government has indicated that it will not appeal, an interest that meets all of the requirements for intervention.

Your Honor, there's been a lot said about standing. I think standing is an issue that should arise at the right time or the right place, and that's the Federal Circuit Court of Appeals. The issue isn't standing in general. It isn't standing in this case. It's standing on appeal. Whether there is standing on appeal should be addressed at the Federal Circuit in the context of the appeal. It's not a fourth element to

intervention.

Even if it were, even if it were, the standing elements, both Article III and permissive -- and prudential standing are met by the fact that a patent, which should not have stood in the way of my client's development, marketing, and investment, is now in the way. As a consequence of that, there is a real injury, and the injury is sufficient -- should be sufficient to award our client leave to intervene in this case.

THE COURT: Okay.

MR. KEISLER: Good morning, Your Honor, and may it please the Court.

APP says that this is not about it trying to inject itself into our patent extension process and the issue is not standing but intervention, but obviously they are trying to inject themselves into this APA case. The issue is, of course, standing because intervention requires them to show a significantly protectable interest. If they don't have standing, they don't have a legally protectable interest.

This is an APA case in which the government announced yesterday that it's chosen to accept the Court's decision and not appeal it, and APP is trying to step into the government's shoes and appeal in the government's place to defend an agency action that the agency has determined that it's no longer going to pursue.

The judicial precedents are completely clear that the

patent laws don't permit intervention of the sort, and it's telling that in our brief and the government's brief, we cited extensively to patent cases involving the PTO and construing the patent laws. APP, in its two briefs, could not cite a single patent case in support of its position. They don't even mention *Boeing v. PTO*, which is the Federal Circuit decision that's completely on point here. Exactly the same situation where the intervenor liked the agency decision, didn't like the district court decision and wanted to go to the Court of Appeals, and the Federal Circuit said it had no standing and it could not proceed with the appeal.

APP says that the Federal Circuit on this appeal wouldn't apply its own law to that question, but that's clearly wrong. The Federal Circuit has said it applies its own law when the issue is standing and its own jurisdiction. That's the *Biotechnology Industrial Organization* case. It says it applies its own law when the issue is what the patent laws require because, of course, no other circuit issues such a decision. It said that in *Minks v. Polaris*.

These cases, which APP is literally silent on, does not even mention, these cases establish that Congress has set forth a specific statutory scheme that precludes intervention. The Supreme Court has said that if you want to carry a case forward when the principal party on your side has dropped out, you have to show that you have standing on your own, that Congress meant

for you independently in order to be able to maintain such an action. Here they can't show that because Congress has done the opposite. It has very severely circumscribed the rights of third-party competitors in PTO cases.

They said if you want to try to bring these kinds of claims, you have to do it in separate litigation, private party versus private party, not in agency proceedings, not in judicial review of agency proceedings under the APA. That's why, when we were before the PTO in the administrative proceedings on our patent term extension application, APP couldn't and didn't participate. That was purely *ex parte*, even though they could have said exactly what Mr. Corrado said here, we want to enter the market and a longer patent will keep us from doing so for a longer period of time.

That's why if the PTO had decided in our favor in the first instance, rather than against us, APP could not have filed an APA challenge in this district court to challenge that even though, again, they could have made the same assertions about their interests. That's why they can't circumvent those restrictions by anointing themselves the sole appellant here.

If they could, then every time a district court ruled against the PTO, it would suddenly be open season. All of the competitors out there who couldn't participate at the agency level, who couldn't bring a case in district court, suddenly they can appear and all come in at the appellate stage. That's

nonsense. It's not the law. If it were the law, if it were the law, surely with all of the patent cases out there and all of the competitors with intense economic interests hovering around those cases, if that was the law, surely APP would have been able to find and cite at least one case where that has actually happened.

Now, none of this is to suggest that they don't have any rights. They do have some rights, but Congress has established a very specific mechanism for the attempt to assert those rights with very specific procedures that APP is here trying to circumvent. What the Federal Circuit said in the *Syntex* case when it affirmed, actually, a decision by Your Honor unanimously, it said the competitor's remedy, if any, must await confrontation with the patent owner in separate infringement litigation.

Congress, in Hatch-Waxman, established very specific procedures for such litigation and it's very carefully structured. It specifically and explicitly in the statute says a competitor in that separate litigation can raise the claimed invalidity of a patent term extension if it can show there was a material failure to comply with the statutory requirements by either the PTO or by the patentholder.

APP doesn't like those procedures. Congress established a very careful set of procedures that balances the rights in those litigations between the patentholders and the

competitors, and APP says in its papers it would be injury for it to be forced to comply with those procedures. It's not injury to be forced to comply with congressionally-mandated procedures. It would flout Congress' will for APP to be able to ignore those procedures, short circuit that process, and then come here by the simple expedient of intervening in this APA action.

There is, in fact, pending litigation under Hatch-Waxman between APP and The Medicines Company. If they think they have a claim that there's a material failure to comply with the extension provisions, they can raise that there, we will contest it, and that's where Congress said that the fight ought to take place.

THE COURT: I understand your position.

Did you want -- 30 more seconds.

MR. CORRADO: Your Honor, very briefly.

It's a different situation. All of the situations they're talking about are situations in which there is an attempt by somebody to get into the patent term extension process. This is not that situation.

This is a situation in which the Court has ruled, very familiar with your ruling obviously, has made a ruling and that ruling has by practical effect extended the patent that otherwise expired. That's different. That's different from the case -- any of the cases they've cited.

They talk about *Boeing*. Again, *Boeing* is a standing case. We don't believe that you get to standing. The issue is intervention. In *Boeing*, the Court said that the only alleged injury was that the plaintiff said that it may seek to practice the technology. It did not allege that Boeing threatened to sue it for infringement or that Boeing's conduct created a reasonable apprehension of such suit.

That isn't the case here. There is a reasonable apprehension of infringement litigation. There is a reasonable apprehension of being blocked entry into the market by this patent. It's that threat, that injury, which would have given standing in *Boeing*, that gives us standing in this case and certainly, I think, is sufficient to meet the requirement of a protectable, significant protectable interest. Thank you.

THE COURT: All right. Well, I don't know about this standing issue. I'm inclined to think you don't have standing, but I'm not prepared to say that at the moment. I might look at this a little further and give you-all something in writing.

I'm going to deny your motion to intervene here. I don't find this intervention to be a timely one. This case has been going on a long time. If you-all thought you had an interest to protect in it, you knew it from the start and you had plenty of time to come in and to make this motion to intervene and to protect your interest if you thought they weren't being adequately protected.

I believe your interests were adequately protected during the trial of this case and just didn't go quite the way you would have liked it to have gone. To allow intervention at this point would be a great prejudice to the plaintiff in this case and would far outweigh any prejudice to the proposed intervenor here.

Your motion to intervene is denied. I may well go on and look at this standing issue. If I do, why, you'll get something from me on that.

Thank you. That takes care of our civil cases, does it not?

All right. We'll adjourn until Monday morning at 9:30.

* * *

(Proceedings concluded at 11:25 a.m.)

CERTIFICATION

I certify, this 13th day of September 2010, that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter to the best of my ability.

/s/
Tracy Westfall, RPR, CMRS, CCR